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EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

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11/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/700,320	Applicant(s) WALTER ET AL.	
	Examiner ERNST V. ARNOLD	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7 have been cancelled. Claims 16 and 17 are new. Claims 8-17 are pending and under examination. Applicant's amendments have necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed 9/23/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 8-10 were rejected under 35 U.S.C. 112, first paragraph and 35 U.S.C. 112, second paragraph. Claims 11-15 were rejected under 35 U.S.C. 112, first paragraph and 35 U.S.C. 112, second paragraph. Applicant has amended the claims and these rejections are withdrawn.

Claims 9 and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Leslie et al. GB 2307857 and claims 12 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Leslie et al. GB 2307857.

Applicant has supplied an MSDS which shows sodium saccharin to melt above 200 C. Accordingly, the rejections over claims 9, 10, 12 and 13 are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 8 and 11 introduce new matter as the claim recites the limitation: "degradable pharmaceutically active substance" There is no support in the specification for this limitation. The limitation of: "degradable pharmaceutically active substance" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. The specification discloses a list of pharmaceutical active substances on page 3, lines 5-35 but does not *ipsis verbis* disclose 'degradable' active substances. For example, the list of antibiotics is not closed and could include silver metal which does not degrade into anything else. There is no guidance in the specification to select "degradable pharmaceutically active substance" and from MPEP 2163.06: "Applicant should therefore specifically point out the support for any amendments made to the disclosure." Applicant has not directed the Examiner to the support in the specification for the amendments. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had

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possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoff et al. US 3872227 or in the alternative is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoff et al. US 3872227.

Hoff et al. disclose formulations for oral administration (Abstract and claims 1-20). Hoff et al. disclose an effervescent tablet in Example 7:

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EXAMPLE 7 — Phenoxymethylpenicillin Effervescent Tablets, 600,000 U each

32 parts of citric acid, 38 parts of sodium bicarbonate, 4.1 parts of sugar, 16 parts of glycine and 1.6 parts of serine are mixed and finely powdered by means of a mill. This mixture is subsequently uniformly moistened, in a kneader, with an alcoholic solution of 0.2 parts of sodium saccharin and dried in a fluidized bed.

The sieved granules are mixed with 7.1 parts of phenoxymethylpenicillin (either as the acid, or employed as the potassium salt, corresponding to 7.8 parts), 0.5 parts of tutti-frutti dry flavoring and 0.5 parts of sodium benzoate.

Effervescent tablets weighing 5.0 g each are prepared from this mixture and when dissolved in water give an aromatic, pleasant-tasting phenoxymethylpenicillin solution.

As is clearly disclosed by Hoff et al., an acidic component (citric acid), a CO₂ donor (sodium bicarbonate), sugar (fusible sugar), and sugar substitute (sodium saccharin) are mixed and finely powdered to produce effervescent tablets. Hoff et al. teach using maltose, mannitol, and sorbitol in the composition (column 2, lines 32-36 and column 3, lines 19-25). In the absence of evidence to the contrary, the 'at least one ingredient' is present in an amount sufficient to stabilize at least one of the CO₂ donor and acidic component and since the ingredients are mixed then it is the position of the Examiner that the CO₂ donor and acidic component are dispersed throughout the substrate. Furthermore, the phenoxymethylpenicillin is inherently degradable in the absence of evidence to the contrary.

With regards to the limitation of "a structure formed by melting said ingredient...", it is the position of the Examiner that this reads on a product by process.

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Please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ stabilized medicament differs and, if so, to what extent, from that of the discussed reference.

Response to arguments:

Applicant asserts that the products are structurally different. The Examiner cannot agree. Hoff et al. make tablets and Applicant makes tablets (page 5, lines 24-25; page 9, line 4; and claim 15). Applicant asserts that the sodium saccharin only comprises 0.2% by weight of the formulation and that the added alcohol of Hoff et al. is not present in an amount to stabilize the effervescent couple or the active ingredient. The Examiner cannot agree. Instant claim 1 does not recite a percent by weight limitation for any ingredient and Applicant's assertion that the amount in Hoff et al. is not sufficient to stabilize the couple or active ingredient is mere argument without proof. The same components are present in Hoff et al. that are instantly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 remains rejected under 35 U.S.C. 102(b) as being anticipated by Leslie et al. GB 2307857.

Comment: A rejection over this prior art was previously made 6/21/02 and was erroneously withdrawn.

Leslie et al. disclose effervescent tablets (Abstract and claims 1-5). Leslie et al. disclose using a binder that melts or softens below 150 C such as polyethylene glycol (page 2 and 3). Leslie et al. disclose in Example 3 on page 4 the instantly claimed composition:

EXAMPLE 3

Tablets were manufactured containing the following ingredients:-

	mg
Tramadol HCl	50.0
Citric acid anhydrous Ph. Eur.	495.0
Polyethylene glycol 6000 Ph. Eur.	100.0
Saccharin sodium Ph. Eur.	2.5
Sodium hydrogen carbonate Ph. Eur.	581.0
Sodium carbonate anhydrous B.P.C.	40.5

2 { The ingredients were blended in a mixer/granulator equipped with heating facility
3 { (heated jacket and/or microwave heater). The temperature was increased to about
60°C whilst mixing until granulation occurred. Then the mixture was cooled and if
necessary classified by passing through a suitable screen/mill. The resulting granules
were compressed into tablets.

In the absence of evidence to the contrary, the 'at least one ingredient' (saccharin; a sugar substitute) is present in an amount sufficient to stabilize at least one of the CO₂ donor and acidic component and since the ingredients are mixed then it is

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the position of the Examiner that the CO₂ donor and acidic component are dispersed substantially throughout the substrate (polyethylene glycol 6000) which has the ingredient as a substantial constituent. Therefore, instant claims 8-10 are anticipated.

With regards to the limitation of “a structure formed by melting said ingredient...”, it is the position of the Examiner that this reads on a product by process. Please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ stabilized medicament differs and, if so, to what extent, from that of the discussed reference.

Response to arguments:

Applicant asserts that the Examiner has taken the position that the mere presence of the ingredients dispersed in polyethylene glycol substrate renders the instant claims anticipated or obvious and that polyethylene glycol is not the ‘ingredient’ of the claims. The Examiner cannot agree. Clearly, the sodium saccharin is the sugar substitute and claim 8 does not recite a melting point limitation for the ingredient. Applicant asserts that nothing can be reasonably described as dispersed in 2.5 mg of solid sodium saccharin that has not been at least partially melted. This is mere opinion

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without proof or evidence. Mixing/blending the components simply disperses one component in another.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 8-10 and 16 remain/are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. US 6071539.

Robinson et al. disclose effervescent granules and thermal heat methods of preparing them comprising an acidic agent, a **hot-melt** extrudable binder capable of forming a eutectic mixture (solid solution) with the acidic agent and active agents (Abstract; tables 1-4; column 13, lines 43-45) and claims 1-16). As can be clearly seen in Table 4 below (with Examiner added emphasis),

TABLE 4

Drug-Containing Hot-Melt Extruded Effervescent Formulations						
Ibuprofen	50	50	0	0	0	30
Chlorpheniramine Maleate	0	0	5	5	0	5
Pseudoephedrine HCl	0	0	0	25	20	
AcDiSol	5	5	0	0	5	5
Microcrystalline Cellulose	20	10	32	20		5
Na Bicarbonate	13	13	15	18	20	15
Citric Acid	12	12	14	15	18	13
PEG 3350	0	10	14	12	10	12
Crosslinked PVP	0	0	5	3	3	3
Explotab	0	0	0	2		2
Mannitol	0	0	5		9	
Xylitol	0	0	10		15	10

formulations with an acidic component (citric acid), a CO₂ donor (bicarbonate), a pharmaceutically active substance (ibuprofen) and at least one ingredient that is a sugar alcohol (xylitol). The Examiner notes that Applicant discloses xylitol as a preferred sugar alcohol for use in the invention (page 4, lines 10-11 of the instant specification) which would inherently have the melting points claimed by Applicant. The mixtures are taught by Robinson et al. to be **hot melt extruded blended mixtures** which would inherently read on a structure formed by melting the substrate and re-solidifying the substrate that has the acidic ingredient substantially dispersed throughout the substrate and a substrate that has the ingredient as a substantial constituent. Therefore, instant claims 8-10 are anticipated. Robinson et al. teach a composition with aspirin, mannitol, an acidic component stearic acid, effervescent granule EG (B) which has sodium bicarbonate, and aspartame which reads on a composition with a CO₂ donor, acid component, a degradable pharmaceutical active ingredient and at least one ingredient

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selected from sugars and sugar substitutes (column 16, lines 19-24 and column 19, lines 57-65):

E.	Ingredients	Amount (% Wt.)
	Aspirin	50
	Mannitol	15
	AVICEL PH101	25.5
	Aspartame	1.5
	Stearic Acid	2.0
	EG (B)	6.0

Thus, instant claim 16 is anticipated.

The temperature of the hot melt extrusion will not exceed 150 C which reads on instant claims 12 and 13 (column 14, lines 1-5). Tablets are disclosed which reads on instant claim 15 (examples 3-9, for example). The rate of effervescence can be controlled by varying the hot-melt extrudable binder which can be xylitol or by the relative amounts of ingredients (column 6, line 32-column 7, line 23). Robinson et al. teach grinding the dried granulation which reads on comminution after cooling of instant claim 14 (column 22, lines 24-26).

With regards to the limitation of “a structure formed by melting said ingredient...”, it is the position of the Examiner that this reads on a product by process. Please note that in product-by-process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference.” MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct

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experimentation in order to determine whether Applicants' stabilized medicament differs and, if so, to what extent, from that of the discussed reference.

Response to arguments:

Applicant asserts that mannitol is not subjected to hot-melt extrusion. However, the Examiner has made a product by process argument and Applicant has not shown a difference. Applicant asserts that Robinson fails the inherency test but has only provided arguments that are not persuasive. Robinson discloses each and every component of the instant composition. Applicant asserts that the instant application has a lowest weight percentage of xylitol of 30% while Robinson teaches 28% xylitol but the claims do not recite this limitation and therefore this argument is without merit. Simply because Robinson does not measure the stability does not mean that stability is absent or the effervescent material is not dispersed in the 'ingredient'. On the contrary, the Examiner has found a prior art composition which teaches each and every element as instantly claimed and Applicant has not shown any difference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-17 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (US 6071539).

Applicant claims:

11 (Currently Amended). A process for producing a stabilized medicament, said stabilized medicament comprising:

(A) an effervescent system comprising:

(i) a CO₂ donor, and

(ii) an acidic component;

(B) a degradable pharmaceutically active substance, and

(C) at least one ingredient selected from the group consisting of fusible sugars, sugar alcohols, and sugar substitutes,

wherein said process comprises the steps of: (a) at least partially melting said ingredient, (b) mixing at least one of said CO₂ donor and said acidic component with said at least partially melted ingredient ~~wherein said ingredient is present in an amount sufficient to stabilize said at least one of said CO₂ donor and said acidic component~~ to form an at least partially molten blend in which said at least one of said CO₂ donor and said acidic component is ~~substantially~~ dispersed, (c) cooling said at least partially molten blend, (d) combining said cooled at least partially molten blend, said pharmaceutically active substance and any remaining portion of said effervescent system and (e) forming said stabilized medicament, wherein said ingredient is present in an amount sufficient to stabilize at least one of said CO₂ donor, said acidic component, and said degradable pharmaceutically active substance.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Robinson et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Robinson et al. is that Robinson et al. do not expressly teach the order of steps (a)-(e) as instantly claimed.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Robinson by performing steps (a)-(e) of instant claim 11, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) ()); and 2) Selection of any order of mixing ingredients is prima facie obvious. (*In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)).

Robinson et al. mixes the components and then hot-melts them while Applicant merely melts one component first and then adds others to the first component. No unexpected results have been argued.

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In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant arguments with respect to Robinson et al. have been addressed above. These arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11 and 14-15 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Leslie et al. GB 2307857.

Applicant claims:

11 (Currently Amended). A process for producing a stabilized medicament, said stabilized medicament comprising:

(A) an effervescent system comprising:

(i) a CO₂ donor, and

(ii) an acidic component;

(B) a degradable pharmaceutically active substance, and

(C) at least one ingredient selected from the group consisting of fusible sugars, sugar alcohols, and sugar substitutes,

wherein said process comprises the steps of: (a) at least partially melting said ingredient, (b) mixing at least one of said CO₂ donor and said acidic component with said at least partially melted ingredient ~~wherein said ingredient is present in an amount sufficient to stabilize said at least one of said CO₂ donor and said acidic component~~ to form an at least partially molten blend in which said at least one of said CO₂ donor and said acidic component is ~~substantially~~ dispersed, (c) cooling said at least partially molten blend, (d) combining said cooled at least partially molten blend, said pharmaceutically active substance and any remaining portion of said effervescent system and (e) forming said stabilized medicament, wherein said ingredient is present in an amount sufficient to stabilize at least one of said CO₂ donor, said acidic component, and said degradable pharmaceutically active substance.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Leslie et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Leslie et al. also teach further processing the granules or agglomerates by breaking them down to give particles for example by milling which reads on comminuted (page 3).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Leslie et al. is that Leslie et al. do not expressly teach step (d) above.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method Leslie et al. by combining the cooled at least partially molten blend with the pharmaceutically active component and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA

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1946) (); and 2) Selection of any order of mixing ingredients is *prima facie* obvious. (*In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930)).

Leslie et al. mixes the components and then hot-melts them while Applicant merely melts one component first and then adds others to the first component. No unexpected results have been argued.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant arguments with respect to Leslie et al. have been addressed above. These arguments are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ernst V Arnold/

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